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Ossiculoplasty with TORP and Omega Connector –

Early Clinical Results and Functional Measurements

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Running head:

Evaluating the performance of total ossicular reconstruction using the Kurz Omega Connector

Keywords:

Omega Connector, Ossiculoplasty, total ossicular replacement prostheses, TORP, titanium prosthesis, middle ear surgery

Abstract

Objective: Among other difficulties, achieving a stable position of a total ossicular replacement prosthesis (TORP) is demanding due to a limited view on the TORP-footplate interface and individual angles between the footplate and tympanic membrane. The Kurz Omega Connector aims at a simplified insertion of the TORP. The performance of total ossicular reconstruction using the Omega Connector was evaluated.

Study Design: Prospective cohort study and experimental measurements with a fresh human temporal bone (TB).

Setting: Tertiary referral center

Patients: 17 consecutive patients receiving total ossicular reconstruction. Historical control group composed of 36 patients.

Interventions: Total ossicular reconstruction using the Omega Connector.

Main Outcome Measures: a) handling of the TORP and Omega Connector intra-operatively, b) functional short-term results compared to a historical control group, c) sound transmission properties with three different connective positions between the TORP and the Omega Connector.

Results: Placing the Omega Connector on the footplate and coupling the Omega Connector to the TORP was straight forward in 65% of cases. A stable final position of the TORP was obtained in 88% of cases. Mean pre- and post-operative air-bone gaps were 36.00 (± 11.05) and 25.29 (±12.25) dB and were almost identical with those in the historical control group ($p = 0.9$). In the experimental measurements, functional outcomes with “Partial Connection” showed almost the same results as those with “Full connection”.

Conclusions: The Omega Connector provides easy handling of the TORP. The short-term functional results were comparable to those achieved previously without the Omega Connector. The TB measurement supports tolerance in connective position between the TORP and the Omega Connector.

Introduction

Ossiculoplasty with total ossicular replacement prostheses (TORP) remains surgically challenging. Among other difficulties, stabilizing the position of the TORP and its connection to the stapes footplate is demanding. This may result in dislocation of the prosthesis both intra- and post-operatively.

At our institution, the Kurz titanium middle-ear prosthesis (Kurz GmbH, Dusslingen, Germany) has been used for several years with dependable results[1]. The characteristics of the prosthesis include low weight, high biocompatibility, adjustable length, and open design. To achieve long-term stability in reconstructed ears, the prosthesis has been secured in the oval window with an intra-operatively fabricated cartilage shoe (Beutner et al.[2]). Positioning the prosthesis, however, remains a challenging procedure as the contact area between the prosthesis and the footplate is not visible during insertion of the prosthesis. The procedure can also be more difficult depending on individual anatomical conditions such as the position of the footplate relative to the tympanic membrane or a prominent facial nerve.

The recently available Kurz Omega Connector (Fig.1), which is made of titanium, employs a ball joint, aiming at a simplified connection of the TORP to the footplate with a better view as well as allowing variation in the attachment position and angle between the TORP and the footplate. The base plate of the Omega Connector is positioned between remnants of the stapes crura which increases stability. The ball joint allows translational and rotational tolerance at the TORP-Omega Connector coupling, and thus, greater stability in the post-operative courses (e.g., during a valsalva maneuver, where the prosthesis shoe may lift off the footplate for a short time and thereby may move out of the oval window) is expected. This study was designed for and focused on a) handling of the TORP and Omega Connector intra-operatively, b) early functional results one year after surgery compared to a historical control group, and c) sound transmission properties with different connective positions between the TORP and the Omega Connector under laboratory conditions.

Materials and Methods

Intra-operative & Prospective Clinical Study

Seventeen consecutive patients receiving ossiculoplasty with TORP and Omega Connector were included in the intra-operative and prospective studies. A Kurz TTP Aerial Vario prosthesis was used in all cases except for a Kurz TTP Tuebingen prosthesis in one case. The underlying middle-ear disease and demographic data were collected.

A standardized questionnaire form was prepared for intra-operative steps, focusing on the application of the Omega Connector. The intra-operative steps that were evaluated included: (1) placing the Omega Connector on the footplate with micro-suction, (2) coupling the TORP to the Omega Connector, and (3) assessing the stability of the reconstructed ossicular chain as a whole. All interventions were performed by the same surgeon.

The mean follow-up duration in the prospective study was 13 months after the surgery (ranging from 2 to 27 months). The functional results were assessed by comparing air-bone gaps (ABGs) pre- and post-operatively at the frequencies 500, 1000, 2000, and 3000 Hz according to the guidelines of the Committee on Hearing and Equilibrium[3] from the American Academy of Otolaryngology, Head and Neck Surgery. When no measurement at 3000 Hz was available, the mean value from 2000 and 4000 Hz was used. The functional results were compared with the corresponding values from a historical control group composed of 36 patients operated previously without the Omega Connector.

Temporal Bone Measurements

Sound transmission with different connective positions at the TORP-Omega Connector interface were assessed by measuring motions of the TORP and the round window membrane (RWM) in an experimental setup. To standardize measurements and exclude inter-individual differences, only a single temporal bone (TB) from the right side (female, 48 years) and artificial eardrums with standardized properties were used.

The ear canal, eardrum, and surrounding bone were removed and replaced by an artificial external ear canal (AEEC, about 3 ml) and an artificial tympanic membrane (ATM) made from a powder-free exam glove (KC300, Kimberly-Clark). The TORP was placed and glued at the center of the ATM so that the longitudinal direction of the TORP was perpendicular to the ATM. The loudspeaker (ER-2, Etymotic Research) and the microphone probe (ER-7C, Etymotic Research) were also placed in the AEEC to deliver sound and measure pressure in the AEEC. The Omega Connector was placed and glued on the top face (the lateral side) of the stapes footplate. Careful attention was given to avoid gluing other structures. With a microscopic view, the stapes footplate with the Omega Connector was aligned horizontally, and the AEEC (also the longitudinal direction of the TORP) was aligned vertically. The relative position between the TORP and the Omega Connector was controlled on a micron scale by stacks of micro-manipulators, to which the AEEC was mounted. Three connective positions between the TORP and the Omega Connector including "Full Connection", "Partial Connection", and "Contact" were defined based on an information sheet provided by Kurz (Fig. 2).

Harmonic sound waves of 9 different frequencies in the range of 0.25 to 8 kHz were delivered to the AEEC one by one via the loudspeaker, and motions of the TORP at its interface to ATM and the round window membrane were measured simultaneously using two Laser LDV systems. A single-point LDV system (OFV-534, Polytec GmbH) was aligned perpendicular to the ATM and used to measure motions of the TORP at its ATM interface. A scanning LDV system (OFV-3001, Polytec GmbH), which could measure multiple points on designated areas with a built-in scanning unit, was used to measure RWM motions. The angular position of the laser beam of the scanning LDV system relative to the round window plane was calculated from coordinates of the reference points in the LDV measurement and anatomical frames (Sim et al.[4]). The coordinates in the anatomical frame were obtained from micro-CT images of the temporal bone. A plane fitting to the annular rim of the round window membrane was defined as the round window plane and was also obtained from micro-CT images. A 15-micron resolution was used for micro-CT scanning of the temporal bone.

Measurements at approximately 200 points of the round window membrane were integrated to calculate volume displacements of the RWM (Stenfelt et al.[5]). It was assumed that points on the RWM vibrate along a direction perpendicular to the round window plane. Retro-reflective beads of 50-micron diameter were coated along the whole RWM to improve reflectivity of the laser beam on the RWM.

To simulate different clinical situations of tympanoplasty, tension of the ATM was controlled with low, middle, and high tensional forces, and measurements with the three different tensions were averaged for sound transmission at each of the connective positions. The tensions of the ATM were set such that a compliance of the middle tension was similar to the typical compliance in a normal human tympanic membrane, a compliance of the low-tension was about 3 times and a compliance of the high-tension was about a third of the compliance of the middle-tension ATM, to simulate surgically reconstructed eardrums. The compliances of the ATMs were confirmed by measurements with a tympanometer (ZODIAC 901, MADSEN Corp.). The middle tension ATM (volume change by 0.3-0.4 ml between 0 and 2 kPa) showed a compliance value similar to one in real human tympanic membranes (the corresponding volume change by 0.4-0.5 ml). The corresponding volume changes in low-tension and high-tension ATMs were around 0.1 and 1 ml, respectively.

Results

Intra-operative & Prospective Clinical Study

The cohort consisted of 10 men (59%) and 7 women (41%) with a mean age of 40 years. Underlying diseases were cholesteatoma in 12 patients (71%), chronic otitis media without cholesteatoma in 2 patients (12%), temporal bone fracture in 1 patient, chronic Eustachian-tube dysfunction with erosion of the stapes superstructure in 1 patient, and middle-ear adenoma in 1 patient. Ten patients (59%) were operated with a canal-wall-up (CWU) technique versus 7 patients (41%) with a canal-wall-down (CWD) procedure. Ossiculoplasty was performed as a second stage procedure in all cases except in the one with chronic Eustachian tube dysfunction. A small recurrent cholesteatoma was found in 3 cases during the second-stage surgery. In 4 cases (24%), ossiculoplasty had been performed earlier and thus were considered as revision ossiculoplasties.

In the control group, underlying diseases were cholesteatoma in 29 patients (81%), chronic otitis media without cholesteatoma in 3 patients (8%), fixed ossicular chain in 2 patients (6%), temporal bone fracture in 1 patient and malformation of the ossicular chain in 1 patient. Twenty patients (56%) had CWU and16 (44%) patients had CWD. A total of 7 patients (19%) had undergone previous ossiculoplasty.

The analysis of the intra-operative steps in application of the Omega Connector as rated by the surgeon is summarized in Table 1. Placing the Omega Connector on the footplate and coupling the TORP to the Omega Connector showed success rates of 65 % for both procedures on their first attempts. The evaluation of the whole reconstructed system was rated as being stable intra-operatively in 15 cases (88%), and a slight instability was shown in 2 cases (12%).

The pre- and post-operative air-bone gaps of both the study population and the control group are shown in Figure 3 and Table 2. In 2 cases (12%), there was no hearing improvement postoperatively and a remaining air-bone gap of about 50 dB was found.

Revision surgery was applied to one of these patients. The TORP was found to be dislocated posterior-superiorly with contact to the bony ear canal while the Omega Connector remained stable on the footplate but without contact to the TORP. Because the patient had undergone ossiculoplasty with TORP twice before, a malleo-stapedotomy was performed with good success. Overall prospective functional outcomes in the study group were compatible to the prospective functional outcomes in the control group. The mean pre-operative air-bone gap was 36.00 dB (SD ± 11.05 dB, range from 23.75 to 56.88 dB) in the Omega Connector group and 36.35 dB (SD ± 12.27 dB, range from 15.63 to 56.88 dB) in the control group. The mean post-operative air-bone gap was 25.29 dB (SD ± 12.25 dB, range from 8.75 to 50 dB) in the Omega Connector group and 25.02 dB (SD ± 18.32 dB, range from 0.63 to 56.88 dB) in the control group. The hearing improvement accounted for 10.47 dB in the Omega Connector group and 11.33 dB in the control group. The differences between the two groups were not significant ($p = 0.9$ by Student's t-test).

Temporal Bone Measurement

Mean TORP displacement at the TM interface and volume displacement of the RWM are shown in Figure 4. At frequencies below 2 kHz, the TORP motions with "Partial Connection" were slightly larger than those with "Full Connection", and the TORP motions with "Contact" were much larger. Above 2000 Hz, the TORP motions with the three connective positions had similar magnitudes. The volume displacements of the RWM showed almost the same magnitude between "Full Connection" and "Partial Connection" along the measured frequency range. The volume displacement magnitudes with "Contact" were smaller than those for "Full Connection" and "Partial Connection".

The trends shown in Figure 4 are more evident in Figure 5, where the TORP displacements at the TM interface and volume displacement of the RWM are represented relative to the corresponding values in "Full Connection". "Partial Connection" showed almost the same magnitudes in the volume displacement of the RWM and only smaller differences of less than 7 dB in the TORP motions compared to the corresponding motions in "Full Connection". The TORP displacements in "Contact" were larger than those in "Full Connection", by more than 20 dB at 500 and 1000 Hz and more than 10 dB at 250 and 1.5 kHz. The volume displacements of the RWM in "Contact" were smaller than those in "Full Connection", by 5 dB at 0.25 kHz, 11 dB at 0.5 kHz, and 15 - 25 dB above 1 kHz.

Discussion

There are many types of prostheses used in ossiculoplasty[6], and outcomes of the surgery are influenced by many additional clinical factors such as surgical technique, underlying middle-ear disease, or Eustachian tube function. According to the literature, the effects of these factors on surgical outcomes still remain controversial. Vassbotn et al.[7] and Schmerber et al.[8] found a significant reduction in hearing improvement in canal wall down situations, whereas in the studies by Alaani et al.[9], Iniguez et al.[10], and Coffey et al.[11], no significant correlation between hearing improvement and type of mastoidectomy was found. Furthermore, none of the authors could find a correlation between functional outcome and underlying middle ear disease at various stages of primary and revision surgery. In order to compare functional outcomes of different types of prostheses with sufficient statistical power, target groups would need large sample sizes with similar surgical techniques and conditions (e.g., CWU/CWD technique, primary surgery/second stage procedure). As this study focused only on evaluating a new method using the Omega Connector in total ossicular reconstruction with a Kurz titanium middle-ear prosthesis, detailed analysis of the different types of prostheses and assessment of surgical techniques and conditions were not performed.

One of the advantages of using the Omega Connector lies in the availability of visual control of the connection between the TORP and the footplate. In conventional total ossicular reconstruction with cartilage, the view of the contact area between the TORP and the stapes footplate may be limited. Thus, positioning the prosthesis in the center of the footplate may be time-consuming and the connection between the TORP and the footplate may not be visually confirmed. Using the Omega Connector, the ball joint of the Omega Connector allows an easy approach of the TORP tip to the Omega Connector with visual check of the continuity of the reconstructed ossicular chain. In our intra-operative analysis, a stable position, as judged by the surgeon, could be achieved in 88% of cases, mostly on the first attempt. Furthermore, because the fabrication of the cartilage shoe was no longer required when using the Omega Connector, about 5 to 10 minutes of operation time was saved. Depending on the institution, this may also justify the costs of the Omega Connector, which currently account for approximately 130 Euros.

In our prospective study, closure of the air-bone gap in the study population was improved by almost the same amount as in the historical control group. The results were comparable with those from other studies analyzing functional outcome of ossiculoplasty with a titanium total ossicular replacement prosthesis, considering the large standard deviations and our relatively small sample size. Alaani et al.[9] reported a mean improvement in air-bone gap of 17.3 dB (SD ± 16.4 dB, n = 32), Vassbotn et al.[7] 19 dB (SD ± 15 dB, n = 35), Ho et al.[12] 21 dB (SD dB ± 14, n=11, exclusive of patients with recurrent disease and patients within less than 6 months after the surgery), Iniguez et al.[10] 8.4 dB (SD not mentioned, n = 94), Coffey et al.[11] 19.5 dB (SD not mentioned, n = 51), and Yung et al.[13] 13.5 dB (SD ± 20.9 dB, n = 30).

The Omega Connector aims to simplify the delicate connection between the TORP and the stapes footplate, allowing tolerance in angular and translational (medial-lateral direction) positions of the TORP thus preventing dislocation of the TORP. This can be considered as the chief advantage of the Omega Connector. Dislocation of a TORP generally occurs when the prosthesis loses its contact to the tympanic membrane or to the stapes footplate, and dislocation rates of 3.2 to 10.8% [8, 10, 14] have been reported with conventional total ossicular reconstruction. In a study by Schmid et al.[15], 14 revision ossiculoplasty cases were examined, and a non-functioning TORP was found in 10 cases. Among these 10 cases, while the prosthesis had no contact with the footplate in 5 cases, the prosthesis was surrounded by scar tissue in 3 cases. These facts underline the significance of stability in the coupling between the prosthesis and the stapes footplate. In our study population of 17 cases, dislocation confirmed by surgery was observed in one, and one other case was highly suspicious with a remaining postoperative air-bone gap of about 50 dB. Our follow-up time of

13 months may not have been long enough to assess long-term stability. However, considering that the most vulnerable period is likely to be the early post-operative course as the prosthesis is not yet held in place by mucosa, the Omega Connector can be considered to provide a reliable prospective stability in coupling between the TORP and the stapes footplate.

Sound transmission with different connective positions between the TORP and the Omega Connector was assessed in an experimental setup using a human temporal bone with artificial tympanic membranes. The plane rubber membrane may not represent characteristics of the real cone-shaped tympanic membrane with its complicated inner structures, and the performance of the TORP and the Omega Connector will differ depending on other clinical factors of tympanoplasty. However, from our result that "Partial Connection" showed almost the same sound transmission as "Full Connection" regardless of the tympanic membrane tension, coupling between the TORP and the Omega Connector is considered to have a translational tolerance of at least 0.15 mm but less than 0.3 mm in the lateral-medial direction. Such a result was still beneficial at frequencies above 4000 Hz, where air-bone gap measurements are not routinely employed due to unreliability of bone conduction measurements.

In summary, the Omega Connector facilitates easy handling of the TORP with prospective stability in coupling between the two. Our experiment with a TB supports tolerance in positioning of the TORP relative to the Omega connector.

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Figure legends

Figure 1. Omega Connector and TORP. The ball joint allows variable coupling angles

Figure 2. Relative position between the TORP and the Omega Connector as used in the experimental setup. The TORP shifted up by 0.15 mm for “Partial Connection” and by 0.3 mm for “Contact”, from “Full Connection”

Figure 3. Pre- and post-operative air-bone gaps of the study group (n=17) and the historical control group (n=36). Vertical bars indicate standard deviations

Figure 4. Mean TORP displacement at the TM interface (left) and volume displacement at the RWM (right). Vertical bars indicate standard deviations

Figure 5. Relative TORP displacement at the TM interface (left) and volume displacement at the RW (right) with respect to “Full Connection”. Vertical bars indicate standard deviations

Table

Table 1. Intra-operative handling of the Omega Connector and TORP as judged by the surgeon

Placement of the Omega Connector on footplate	11 (65%) at first attempt 6 (35%) adjustment necessary
Coupling TORP to Omega Connector	11 (65%) at first attempt 6 (35%) more than one attempt necessary
Stability after connection	15 (88%) stable 2 (12%) slight instability
Alignment to tympanic membrane	10 (59%) perpendicular 7 (41%) angled

Table 2. Characteristics of the surgical study groups

Group	Number of Patients	Mean Preoperative Air-bone Gap (SD)	Mean Postoperative Air-bone Gap (SD)
Omega Connector group (Study population)	17	36.00 dB (11.05)	25.55 dB (11.53)
Historical control group	36	36.35 dB (12.27)	25.02 dB (18.32)

Fig. 1

Fig. 2

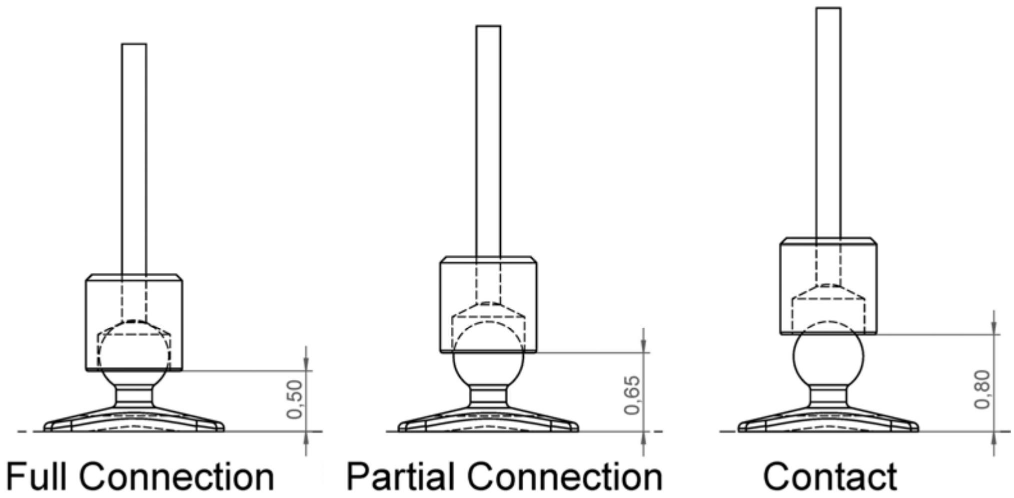


Fig. 3

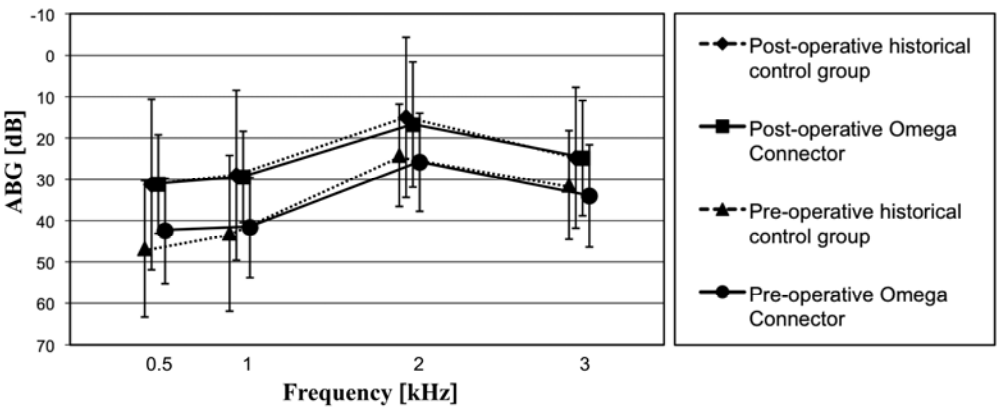
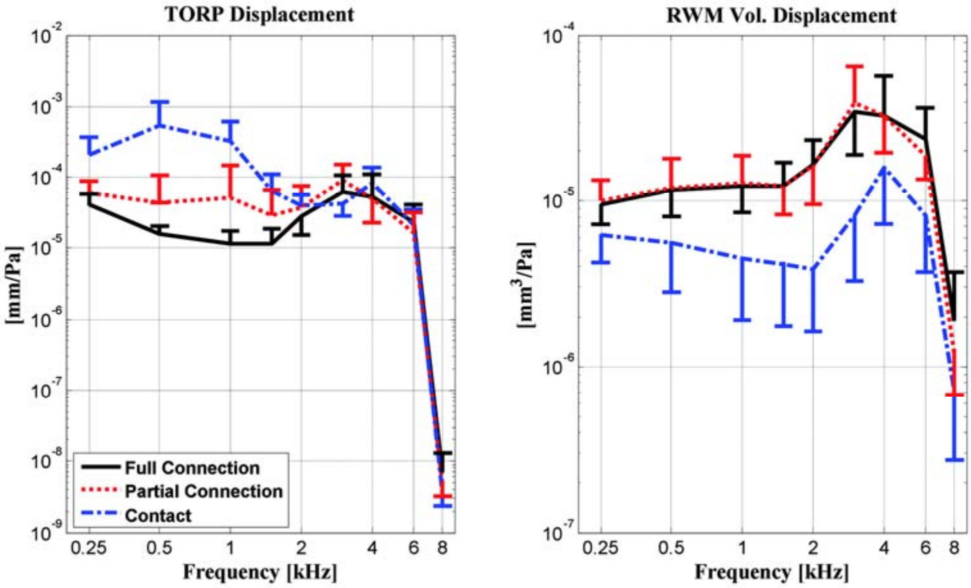
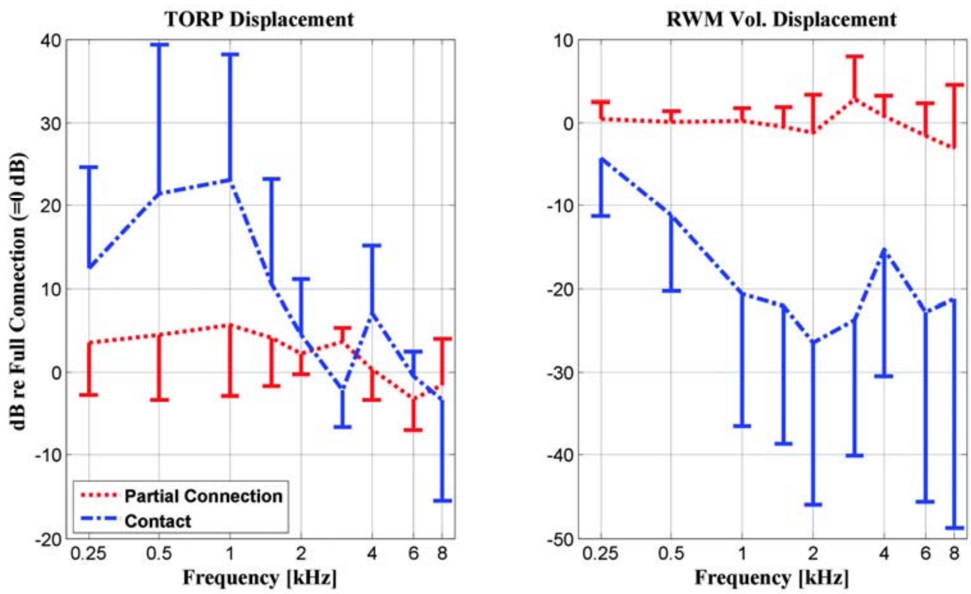


Fig. 4



TORP Displacement
RWM Vol. Displacement
[mm/Pa]
[mm³/Pa]
Full Connection
Partial Connection
Contact
Frequency [kHz]
0.25
0.5
1
2
4
6
8

Fig. 5



TORP Displacement
RWM Vol. Displacement
dB re Full Connection (=0 dB)
Partial Connection
Contact
Frequency [kHz]
0.25
0.5
1
2
4
6
8